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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/825,786 | 04/04/2001 | Gerald W. Mills | 723.035US1 | 1321 |

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EXAMINER

JUNG, WILLIAM C

ART UNIT PAPER NUMBER

3737

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/825,786 | Applicant(s) MILLS ET AL. | |
| | Examiner William Jung | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21, 23-26 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21, 23-26 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 10-21, 23-26, and 29-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 10-17, 20, 21, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Franck et al* (US 6,529,765 B1) in view of *Truwit* (US 6,206,890 B1).

Franck et al substantially anticipate all claimed features in claims 10-17, 20, 21, 30, and

31.

Claims 10 and 20: Franck et al disclose a method and apparatus where an alignment system as shown in figures 3, 5, 7, 9, and 10 where the system comprises a base 330 affixed to a patient's surface, an insertion guide 710 (in figure 9) having an opening and insertion axis through the opening, an adjustable joint attached to a distal end of the insertion guide, and coupled to the base plate 724, a local adjustment device attached to the adjustable joint 840, an actuator coupled to the local adjustment device, and a control module 580 in remote communication with the actuator and in communication with the imaging device 560 to align the insertion axis with the target location (col. 3, line 65 – col. 4, line 65; col. 7, line 57 – col. 8, line 47; col. 8, line 50 – col. 9, line 6; col. 11, line 40 – col. 12, line 41). Although, Franck et al do not specifically

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disclose remote actuator spaced apart from the local adjustment device to locate the actuator outside an imaging region of the imaging device while the local adjustment is within the imaging region of the imaging device, such disclosure is well known in the art. For example, Truwit shows in figures 30 to 32 where mechanical remote actuation and control device 3000 which includes the actual trajectory guide 3001 which is attached to a patient and a second trajectory guide spaced apart remotely from the patient and imaging device (col. 14, line 31 – col. 15, line 20). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Truwit's remote actuator with Franck et al's device above as described above.

Claim 11: Franck et al disclose the control module as described above is a workstation. However, the miniaturization of computer (microcomputer) is purely a design choice since the control function of the control module does not change with the size of the control module.

Claim 12: Franck et al disclose that the image-guided procedure such as one described above can be used with variety of medical imaging system including MRI device (col. 1, lines 43-50).

Claims 13-15: Franck et al disclose fiducial markers 340 where the markers provide first reference coupled to the insertion guide to locate the insertion axis in 3D space relative to the patient (col. 8, lines 3-31).

Claims 16 and 17: Franck et al disclose a reference device 730 in which it provides LED to locate the insertion axis in 3D space relative to the patient (col. 12, lines 1-13).

Claim 21: Franck et al as shown in figures 3, 5, 7, and 9 where the coupling at the base includes attached the base directly to the skull of the patient (col. 8, lines 5-11).

Claims 29 and 32: Franck et al do not explicitly disclose in writing the structure of the actuator being a ball and socket joint. In figures 11, 17c, and 19, Franck et al illustrates socket joint with round structure 914 in round shape. Although, Frank et al's disclosure is silent in ball and socket joint, it would be obvious to view figure 11 as ball and socket without complete drawing of 914 where ball and socket joint is used in the art as evident by Truwit's (6,206,890 B1) use of the same structure for the insertion guide (see figure 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al with the ball and socket joint actuator as disclosed by Truwit to provide accurate actuation of the insertion guide as disclosed by Franck et al.

Claims 30 and 31: Franck et al further disclose the local adjustment described above where it includes slide coupled to the insertion guide 850 as shown in figure 10.

4. Claims 18, 19, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Franck et al* and *Truwit* as applied to claims 10 and 20 above, and further in view of *Lee et al* (US 3,893,449).

Franck et al and Truwit substantially disclose of all claimed invention in claims 18, 19, and 23-26. However, Franck et al do not disclose rotary motor coupled to the local adjustment device and the control of the device via potentiometer. Lee et al discloses of an imaging device placed on a patient with remote control of the device to align the imaging device to an appropriate location. Lee et al also teaches that the location of the medical device such as ultrasound is referenced to identify the position using potentiometer (col. 1, line 59 – col. 2, line 11). Lee et al also disclose in figures 2 and 11 where the control mechanism includes pin joint actuator with rotary motor with rotating cable drive (col. 5, lines 36-64). Therefore, it would

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have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al's aligning imaging device to teachings of Lee et al's position referencing system to achieve the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ
October 31, 2005


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